- 2. (Amended) A composition for administration to animals including a combination of:
 - (a) at least one anti-inflammatory agent selected from the group comprising:
- i) green-lipped mussel extract (GLME) and/or a pharmacologically active green lipped mussel product, and
 - ii) shark cartilage; with
 - (b) at least one enhancing agent selected from the group of:
- i) a bark or plant product or bark or plant extract, exhibiting any one of antioxidant, anti-arthritic, and anti-inflammatory properties, and
 - ii) shark cartilage;

and wherein for a composition including just one member from each group, the selected members must be different.

REMARKS

Claims 1-19 and 22-34 are pending in this application.

Restriction of Invention Requirement

In the Office Action dated March 26, 2003, the Examiner stated that pending claims 1-19 and 22-34 are subject to a restriction under 35 U.S.C. §121 and 372. According to the Examiner, the application does not relate to a single general inventive concept under PCT Rule 13.1 but rather includes two separate inventions, and the Examiner has required that the application be restricted, under 35 U.S.C. § 121, to one of the inventions as follows:

Group I: claims 1-17 and 23-34, drawn to a composition; and

Group II: claims 18-22, drawn to a method for treating a human suffering from a condition.

According to the Examiner, the technical feature linking the two groups of inventions appears to be that "they all relate to a composition comprising an anti-arthritic agent (green-lipped mussel extract) and at least one enhancing agent (an extract that exhibits anti-oxidant properties – fish oil)." The Examiner stated that this feature does not constitute a special

technical feature as defined by PCT Rule 13.2 so as to form a single general inventive concept, since it "does not define a contribution over the prior art", namely, because a cited reference teaches a composition comprising green-lipped mussel extract and fish oil for a synergistic anti-inflammatory effect.

The undersigned attorney first thanks the Examiner for the courtesies extended during a telephone interview earlier this week regarding this matter. This attorney attempted to explain a misunderstanding in the Examiner's interpretation of the claims, and the Examiner advised this attorney to file a Response including such arguments. In response to the restriction requirement, therefore, Applicants traverse this restriction requirement.

Applicants point out to the Examiner that a basic misunderstanding and misreading of the claims has apparently led to the issuance of a restriction requirement. Under the Examiner's misreading of claims 1 and 2, claim 1(b)(i) comprises either "a bark product" or an "extract exhibiting antioxidant properties", and claim 2(b)(i) comprises either "a bark or plant product" or an "extract exhibiting any one of antioxidant, anti-arthritic, and anti-inflammatory properties". Accordingly, the Examiner stated that the technical feature linking the two groups of inventions is "a composition comprising an anti-arthritic agent ... and at least one enhancing agent ...," and the Examiner names "fish oil" as one "extract that exhibits anti-oxidant properties".

However, Applicants advise the Examiner that fish oil is not an enhancing agent that is within the scope of the claims. Contrary to the reading made by the Examiner, claim 1(b)(i) should not be read as either "a bark product" on one hand or an "extract exhibiting antioxidant properties" on the other hand, but rather either "a bark product" on one hand or a "bark extract" on the other hand, either of which exhibits antioxidant properties. Similarly, claim 2(b)(i) should not be read as either "a bark or plant product" on one hand or an "extract exhibiting any one of antioxidant, anti-arthritic, and anti-inflammatory properties" on the other hand, but rather either "a bark or plant product" on one hand or a "bark or plant extract" on the other hand, either of which exhibits any one of antioxidant, anti-arthritic, and anti-inflammatory properties. The specification discloses that the extract referred to in claims 1(b)(i) and 2(b)(i) is either a bark or

plant abstract, as at page 4, lines 19-29, at page 7, line 28 – page 8, line 8, and at page 10, lines 9-16. Applicants have amended claims 1 and 2 to clarify the intended reading of these claims.

A correct reading of claims 1 and 2, as amended, makes clear that the enhancing agent in part (b) of claim 1 must be selected from the group consisting of (i) a bark product or a bark extract, exhibiting antioxidant properties, and (ii) shark cartilage, and that the enhancing agent in part (b) of claim 2 must be selected from the group consisting of (i) a bark or plant product or a bark or plant extract, exhibiting any one of antioxidant, anti-arthritic, and anti-inflammatory properties, and (ii) shark cartilage. Fish oil, as suggested by the Examiner as an enhancing agent, does not fall into any of these categories and thus, while it may be considered generally an extract that exhibits anti-oxidant properties, cannot be considered "an enhancing agent" within the scope of either claim 1 or claim 2. Thus, the Examiner's cited reference that teaches a composition comprising green-lipped mussel extract and fish oil for a synergistic anti-inflammatory effect is beside the point and not relevant to the claimed invention.

Accordingly, on the basis of the above arguments and amendments, Applicants assert that there is a single general inventive concept between the composition and method claims under PCT Rule 13. The enhancing agents referred to in the method claims are the same as those of referred to in claims 1 and 2, and the Examiner has not found any prior art that teaches the use of (a) at least one anti-inflammatory agent selected from the group comprising (i) green-lipped mussel extract and/or a pharmacologically active green lipped mussel product, and (ii) shark cartilage, with (b) at least one enhancing agent selected from the group of (i) a bark product or bark extract, exhibiting antioxidant properties, and (ii) shark cartilage. Thus, because this feature constitutes a special technical feature under PCT Rule 13.2 so as to form a single general inventive concept, since it defines a contribution over the prior art, there is no need to restrict the invention as claimed.

Election of Species Requirement

In the Office Action dated March 26, 2003, the Examiner also stated that claims 1-19 and 22-34 are subject to an election of species requirement because they are allegedly directed to

more than one species of generic invention. The Examiner asserted that there is a lack of unity of invention because the species, enumerated by the Examiner as (1) an anti-arthritic agent, (2) an enhancing agent and (3) a condition, do not relate to a single inventive concept under PCT Rule 13.1 for a lack of the same or corresponding technical features under PCT Rule 13.2. Quoting PCT Rules 13.1 and 13.2, the Examiner stated that the search would be burdensome because, due to the great number of chemical compounds with vastly different chemical structures and properties, one would have to search several different classes and subclasses.

Applicants first state that the Examiner's enumerated species appears to have little basis in the claimed invention. The Examiner's first named species, an anti-arthritic agent, does not appear to relate to the claims on file. The claims refer to a composition having an anti-inflammatory effect, and no species of claims relates to "an anti-arthritic agent". The only reference to an anti-arthritic agent is in claim 2, wherein subpart (b)(i) refers to an enhancing agent, which exhibits "any one of antioxidant, anti-arthritic, and anti-inflammatory properties". In addition, the Examiner's third species, a condition, seems unreasonable as it only appears in one claim, namely claim 22, which claims a method for treating a human suffering from one or more conditions selected from a group. The Examiner has not sufficiently explained how or why the conditions listed only in claim 22 constitute a genus, especially when the method claimed therein is very specific.

Applicants traverse the election requirement, on the grounds that, even under PCT Rule 13.2, the number of possible compositions claimed in these claims is not nearly large enough to make searching of the combinations burdensome. First, with respect to claim 1 and 2, the second of the Examiner's named species, an enhancing agent, has been amended and narrowed as discussed above. Now, each of the groups (a) and (b) in these two claims contains only two possible elements, and there are thus only eight (8) possible combinations of the elements of the compositions. Applicants assert that this is certainly not a burdensome search, especially since elements (a)(ii) and (b)(ii) are identical in both claims 1 and 2, and a different class search would not have to be done for these elements. Similarly, Applicants submit that searching regarding the Examiner's third species of invention (a condition) would not be burdensome as it only appears

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in one claim (claim 22) and would not be too large to search and examine with the rest of the application.

According to currently recommended U.S. Patent and Trademark Office policy, the Examiner is specifically authorized to contact the undersigned in the event that a telephone interview would advance the prosecution of the case. In particular, in the event that a discussion between the Examiner and an attorney for Applicants would assist in overcoming the restriction and election requirements, the Examiner is requested to contact the undersigned in order to conduct a telephone interview.

Reconsideration of the present application, as amended, is requested. Applicants respectfully submit that all the claims pending in this application are patentable. An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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DAVIDSON, DAVIDSON & KAPPEL, LLC 485 Seventh Avenue, 14th Floor New York, NY 10018 (212) 736-1940 Application of:

HASHMI, Syed, et al.

Serial No.:

10/031,581

Filed:

January 18, 2002

VERSION OF CLAIM AMENDMENTS WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

- 1. (Amended) A composition for administration to animals including a combination of:
 - (a) at least one anti-inflammatory agent selected from the group comprising:
- i) green-lipped mussel extract (GLME) and/or a pharmacologically active green lipped mussel product, and
 - ii) shark cartilage; with
 - (b) at least one enhancing agent selected from the group of:
 - i) a bark product or bark extract, exhibiting antioxidant properties, and
 - ii) shark cartilage;

and wherein for a composition including just one member from each group, the selected members must be different.

- 2. (Amended) A composition for administration to animals including a combination of:
 - (a) at least one anti-inflammatory agent selected from the group comprising:
- i) green-lipped mussel extract (GLME) and/or a pharmacologically active green lipped mussel product, and
 - ii) shark cartilage; with
 - (b) at least one enhancing agent selected from the group of:
- i) a bark or plant product or <u>bark or plant</u> extract, exhibiting any one of antioxidant, anti-arthritic, and anti-inflammatory properties, and
 - ii) shark cartilage;

and wherein for a composition including just one member from each group, the selected members must be different.